POEM
Pediatric Oncology
East & Mediterranean

The following is a brief introduction of IRB and Categories of review of research involving human subjects, extracted from the American University of Beirut resources. However, please make sure to follow your institution's IRB guidelines.

Institutional Review Board (IRB) Brief Introduction

Research Studies that involve human subjects require IRB's review, governance and approval. Other than reviewing and approving all new research proposals, the IRB as well conducts annual continuing reviews and issues renewals.

The IRB categorizes research submissions and hence IRB applications according to the level of risk for human subjects participating in research studies.[1]

Categories of review of research involving human subjects:

Exempt/Limited Review

Studies that involve "less than a minimal risk" to participants are processed as "Exempt" IRB applications.[2]

"Under the provisions of §46.104 of the Common Rule, several areas or types of research that, although involving human subjects are exempt from the IRB's review and approval process (refer to IRB website, resource documents). These are activities that do not expose human subjects to any physical, social or psychological risks"[3]

Expedited Review

Studies that are expected to incur "a minimal risk" are processed as "Expedited" research applications. [4]

The general categories of research in which expedited review may apply are the following:

1. "Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

[1] *https://www.aub.edu.lb/irb/Pages/Aboutus.aspx*
[2] *https://www.aub.edu.lb/irb/Pages/Aboutus.aspx*
[3] *https://www.aub.edu.lb/irb/Documents/irb_manual%20-%20revised-%20Version%208%20February%202020-.pdf*
[4] *https://www.aub.edu.lb/irb/Pages/Aboutus.aspx*

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

   (a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week;

   or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
   (a) Hair and nail clippings in a nondisfiguring manner;
   (b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
   (c) Permanent teeth if routine patient care indicates a need for extraction;
   (d) Excreta and external secretions (including sweat);
   (e) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
   (f) Placenta removed at delivery; 36
   (g) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
   (h) Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
   (i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
   (j) Sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:
   (a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
   (b) Weighing or testing sensory acuity;
   (c) Magnetic resonance imaging;
   (d) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electro-retinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
   (e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:
(a) Where: (i) The research is permanently closed to the enrollment of new subjects; (ii) All subjects have completed all research-related interventions; and (iii) The research remains active only for long-term follow-up of subjects;
or (b) Where no subjects have been enrolled and no additional risks have been identified;
or (c) Where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

N.B. Note that categories 8 and 9 are expedited review procedures that apply only to the required continuing review by the IRB, not the initial review of a new application." [5]

Full Board Review

Studies expected to incur "more than minimal risk", as well as those referred to the board by the IRB chair and those disapproved after an expedited review, fall in the "Full Board Review".

The IRB has a specific mechanism to review and handle each of the above categories, which also assists the researchers identify which category fit their research protocols best. "Furthermore, the IRB has the authority to approve submitted research protocols, require modifications to submitted protocols, deny approval of submitted protocols, and/or suspend or terminate already approved protocols. The IRB processes amendments to approved research proposals, review reports of adverse events, handles instances of protocol deviations, non-compliance and assist

[5] *https://www.aub.edu.lb/irb/Documents/irb_manual%20-%20revised-%20Version%208%20February%202020-.pdf*

HRPP in processing allegations and complaints; It also manages protocol specific and relevant conflict of interest."[6]

Note: You are encouraged to check with your institution's IRB regarding institution specific requirement or more information.

[6] *https://www.aub.edu.lb/irb/Pages/Aboutus.aspx*

References

- https://www.aub.edu.lb/irb/Pages/Aboutus.aspx
- https://www.aub.edu.lb/irb/Documents/irb_manual%20-%20revised-%20Version%208%20February%202020-.pdf